

Appln No. 10/045,184  
Amdt date August 18, 2004  
Reply to Office action of May 20, 2004

**REMARKS/ARGUMENTS**

Claims 1-13, 17-23 are currently pending in the application. Claims 14-16 are canceled without prejudice. Claim 13 has been broadened to include the subject matter of canceled claims 14-16. Claim 13 has also been rewritten in independent form, as suggested by the Examiner. Support for the amendment to claim 13 can be found throughout the specification, for example, in the originally submitted claims 13-16, and on page 9, line 3 to page 17, line 32. New claims 17-23 are added. Support for these new claims can be found throughout the specification, for example, on page 4, line 4 to page 5, line 8, and page 9, line 3 to page 17, line 32. No new matter has been added.

The typographical error in claim 13 has also been corrected. Applicant thanks the Examiner for pointing it out.

Reconsideration is respectfully requested.

**I. Rejection under 35 U.S.C. §112**

On page 2 of the office action, the Examiner rejected claims 13-16 under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant respectfully submits that it is clear from the examples in the specification that the % recited in claims 13-16 represents % by wt. of the total weight of the second component.

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Nevertheless, Applicant has amended claim 13 to obviate the rejection and submits that the claim now pending complies with 35 U.S.C. §112 second paragraph. Reconsideration is respectfully requested.

II. Rejection under 35 U.S.C. § 103(a)

A. On page 3 of the Office Action, claims 1-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332).

The Examiner noted that the primary reference discloses a two-chambered syringe for tooth whitening where the first chamber contains peroxide, and the second chamber a basic element. See col. 3, lines 47-53. The examiner then contends that since the peroxides and the basic element are admixed immediately prior to application, they are "adapted to be admixed and applied to the teeth from a dental tray for sustained contact". Though the Examiner also admits that the primary reference does not specifically disclose a mixture of hydrogen peroxide and carbamide peroxide, the Examiner notes that the secondary reference teaches that it is known to use mixtures of the two in varying concentrations to provide "bleaching compositions having a wide spectrum of bleaching agent concentrations". Therefore, the Examiner concludes that it would have been obvious to have combined the individually disclosed hydrogen peroxide and

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carbamide peroxide of the primary reference in a two-component tooth bleaching gel in varying concentrations, motivated by the desire to provide "bleaching compositions having a wide spectrum of bleaching agent concentrations" as taught by the secondary reference.

Further, with regard to dependent claims 3-10, the Examiner contends that "it is well settled that normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; and that experimentation to find workable conditions generally involves not more than the application of routine skill in the art of chemical engineering. " *In re Aller* 105 USPQ 233. Similarly, the Examiner also contends that the determination of optimal values within a disclosed range is generally considered obvious. *In re Boesch*, 205 USPQ 215.

Finally, with regard to claim 2, the Examiner contends that though the primary reference teaches the use of the gelling agent hydroxyethylcellulose and not hydroxypropylcellulose, it is well settled that a prima facie case of obviousness may be based upon structural similarity. See co. 5, line 57; *In re Gyunik*, 596 F.2d 1012, 201 USPQ 552 (CCPA 1979); *In re Grabiak*, 226 USPQ 870.

Applicants respectfully traverse the rejections.

The Examiner admits that the primary reference does not disclose a mixture of hydrogen peroxide and carbamide peroxide.

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Applicant submits that the primary reference also does not provide any motivation for one of skill in the art to use a mixture of hydrogen peroxide and carbamide peroxide in a two-component whitening gel. While the secondary reference mentions that hydrogen peroxide solutions and carbamide peroxide solutions can be mixed together in varying concentrations, it is mainly concerned with a one-component composition having sufficient shelf life, and not a two-component composition. See col. 3, lines 34-40 and col. 5, lines 59-63. In addition, the secondary reference also teaches that the "type and amount of hydrogen peroxide to be used will depend on the desired peroxide concentration in the final dental bleaching composition. In general, it will be preferable to use concentrated hydrogen peroxide solutions when it is desired to manufacture a bleaching composition having high concentrations of bleaching agent. Lower concentrated hydrogen peroxide solutions and/or carbamide peroxide and/or sodium perborate are generally used when it is desired to manufacture a bleaching composition having lower concentrations of bleaching agent." See col. 5, lines 49-59. The reference then goes on to disclose examples where only hydrogen peroxide alone is used at levels of between 3.5 and 90%. See col. 9, line 51 to col. 12, line 18.

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Claim 1 of the present application discloses a two-component dental bleaching system comprising a first component comprising both carbamide peroxide and hydrogen peroxide.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicant respectfully submits that there is no suggestion or motivation in the primary reference to combine its teaching of a two component system with that of a one-component system to arrive at a two component system of claim 1 of the present invention. In addition, applicant submits that the secondary reference teaches away from such combination when it teaches that "it will be preferable to use concentrated hydrogen peroxide solutions when it is desired to manufacture a bleaching composition having high concentrations of bleaching agent" (col. 5, lines 52-55). Therefore, applicant submits that claim 1 is patentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332).

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Dependent claims 2-10, which are dependent from independent claim 1,

were also rejected under 35 U.S.C. §103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332). While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2-10 are also in condition for allowance.

Applicant respectfully request that the rejection of claims 1-10 under 35 U.S.C. § 103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332) be withdrawn.

B. On page 5, claims 1, 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332), the combination being taken further in view of Norfleet et. Al. (USP 5,486,350).

The Examiner admits that the combined teaching of Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332) differs from claim 11 and 12 in so far as the incorporation of potassium nitrate (claim 11) and tetrapotassium pyrophosphate (claim 12)

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is not specified, and that the tertiary reference does not specifically disclose bleaching gels. However, the Examiner notes that the tertiary reference teaches that it is well known to incorporate potassium nitrate and tetrapotassium pyrophosphate into dentrifices, as such mixtures are used to reduce tooth sensitivity, with sodium fluoride being used to stabilize the pyrophosphate. See col. 1, lines 9-18, and col. 4, lines 37-49. Therefore, the Examiner concludes that it would have been obvious to have added sodium fluoride, potassium nitrate and tetrapotassium pyrophosphate to the bleaching gels suggested by the combined teachings of the primary and secondary, motivated by the desire to increase the comfort of patients having sensitive teeth while undergoing the bleaching procedure since those compounds are known sensitivity reducers as taught by the tertiary reference.

Applicant respectfully traverses the rejection.

As discussed above, claim 1 is patentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332). There is no teaching or motivation in the primary reference to combine its teaching with that of a one-component system to arrive at a two-component system of claim 1 of the present invention. In addition, the secondary reference seems to teach away from such combination when it teaches that "it will be preferable to use concentrated hydrogen peroxide solutions when it is desired to

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manufacture a bleaching composition having high concentrations of bleaching agent". Therefore, claim 1 is patentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332).

At the same time, there is also no motivation or teaching by the primary reference to look to a tertiary reference (Norfleet et. Al. (USP 5,486,350)) that only concerns a desensitizing, anti-tartar dentrifice to supply any deficiency in its teaching. See col. 1, lines 9-18. Also, the mere presence of potassium nitrate, tetrapotassium pyrophosphate and even fluoride in such a dentrifice does not supply the necessary teaching or motivation to combine the teaching of the primary reference with that of the secondary reference. The three criteria for establishing a *prima facie* case of obviousness are clearly not satisfied. MPEP § 2142. Applicant respectfully submits that claim 1 is patentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332), the combination being taken further in view of Norfleet et. Al. (USP5,486,350).

Dependent claims 11 and 12, which are dependent from independent claim 1, were also rejected under 35 U.S.C. § 103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332), the combination being taken further in view of Norfleet et. Al. (USP5,486,350). While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of



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the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 11 and 12 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 1, 11 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332), the combination being taken further in view of Norfleet et. Al. (USP5,486,350).

### III. Allowable subject matter

Applicant thanks the Examiner for favorable consideration and allowability of claims 13-16 and have followed the Examiner's suggestion in rewriting claim 13 in independent form. The claim is also broadened to include the subject matter of claims 14-16. Reconsideration is respectfully requested.

### IV. Conclusion

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

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If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, William P. Christie at (949) 476-0757 Ext. 3202.

Respectfully submitted,

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